

Exhibit 4

96-433-810

PROPERTY OF ADVANCED CARDIOVASCULAR SYSTEMS, INC.



Advanced Cardiovascular Systems, Inc.

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NAME Larry Wasicek
DEPT. 1471
LAB. NOTEBOOK NO. 1260
ISSUE DATE 1/25/94
RETURN DATE 9/27/96

RETURN TO DOCUMENT CONTROL FOR ARCHIVING.

TITLE:

PEEK Post Process Evaluation

JW 5/25/94

OBJECTIVE:

To determine the post extrusion process conditions for different extrusion runs. Five of the extrusions were completed at ACS and one extrusion at Accutech.

MATERIALS:

Description	Part Number	Source	Conditions/Comments
PEEK	EXTR.# 10-552-1	in-house	Water bath was 8 degrees (c)
PEEK	EXTR.# 10-554-1	in-house	Was air cooled extrusion
PEEK	EXTR.# 10-553-1	in-house	Water bath was 70 degrees (c)
PEEK	EXTR.# 10-543	in-house	
PEEK	EXTR.# 581	in-house	
PEEK	AP0001842	outside vendor	

Notes:

Runs number 543 and 581 have similar extrusion run conditions.

PROCEDURES:

Necking: Place a .031" Teflon mandrel inside the PEEK and with a hot box set at 475 degrees (f) try to neck the material. Necking is done at the end of the Teflon mandrel while tension is applied where there is no mandrel.

Expanding: Use a .042" ID TFE sheath and hot box set at 500 (f) with 110 psi and expand.

Rating Matrix

Part Number	Expanding	Necking	Surface
EXTR.# 10-552-1	N/A	N/A	Terrible
EXTR.# 10-543	Good	Good	Bumps
EXTR.# 10-554-1	Good	Good	Good
EXTR.# 10-553-1	Good	Good	Terrible
EXTR.# 581	Good	Good	Bumps
AP0001842	Good	*OK	Very Good

* See dimensions below

Comments:**Expanding**

EXTR.# 10-552-1	Material was not tested because of the terrible surface finish.
EXTR.# 10-543	Easily performed and controllable.
EXTR.# 10-554-1	Easily performed and controllable.
EXTR.# 581	Easily performed and controllable.
EXTR.# 10-553-1	Easily performed and controllable.
AP0001842	Easily performed and controllable.

Distribution: B. Ainsworth, D. Cox, E. Leopold, S. Schaible, J. Lee, E. Williams, R.Cherry

Joseph C. Saturni / CS 5/25/94

Necking:

EXTR.# 10-552-1
EXTR.# 10-543
EXTR.# 10-554-1
EXTR.# 581
EXTR.# 10-553-1
AP0001842

Material was not tested because of the terrible surface finish.
Easily performed and controllable. At 475 (f) the OD was .033"
Easily performed and controllable. At 475 (f) the OD was .033"
Easily performed and controllable. At 475 (f) the OD was .033"
Easily performed and controllable. At 475 (f) the OD was .033"
Easily performed and controllable. At 475 (f) the OD was .036"

CONCLUSION:

- Except for extrusion #10-552-1, all of the extrusions were able to be tested.
- With regards to the necking process, the in house extrusions were able to obtain thinner walls. I believe this was due to the elongation properties they possess.
- Expanding was about equal for all except for extrusion #10-552-1.
- The in-house extrusion process needs to improve the outer surface finish.
- The Accutech surface finish, I would consider clinically acceptable.

RECOMMENDATION:

- Another post process that will require investigating is proximal markers.
- During the expanding process the TFE becomes very soft and probably dimensionally unstable due to the high heat. Glass molds may have to replace the TFE capture tube.
- Advise the Safety Department of the high temperature processing condition.
- Continue improving in-house extrusion process.

LDW 5/25/94

Joseph C. Sturner
KS 5/25/94

Alternative Extrusion Grade Resins For PEEK

6/94

L. Wasicek

Objective:

To determine if there is a commercially available extrusion grade resin which would give us a better performing proximal shaft than the Victrex PEEK material (grade 381G).

Background/History:

In January of 1994, there was a brain storming meeting regarding alternative technologies to the Elastinite IM. Elastinite was estimated at \$25-35 per tube/catheter. At this point in time, there was a heavy concern with the high cost of Elastinite and that it would not be a viable design option. Also, the thoughts were the market would be very cost sensitive in 1995-1996 and catheter prices would be around \$400/catheter. We already started investigating PEEK as a proximal stiff shaft as a Elastinite IM replacement. The idea came up to investigate other advanced polymers such as engineering resins as shaft materials and determine the best one.

Research Procedures:

Held brain storming meeting regarding Elastinite replacement. See memo dated 1/14/94.

Research high modulus extrusion grade polymers. Reference article in Modern Plastics (Nov. 1993) titled, Advanced Thermoplastics Electronics Markets Hum Along While Military and Aerospace Falter

Call vendors and obtain material property data information. Compile spreadsheet with material property data. (see attached)

Held meeting and selected resins to investigate (see memo dated 3/2/94).

Selection Criteria:

Very high modulus

Low moisture absorption < 1.6%

Elongation > 50%

Order resins.

Extrude resins.

Evaluate and test materials

Distribution:

J. Lee

D. Cox

B. Ainsworth

E. Leopold

L. Wasicek LW 6/9/94

cc: J. Becker

Joseph C. Latano JCS 6/9/94
L. Wasicek 6/9/94

Materials:**High Temperature Engineering Resins:**

Polyetheretherketone (PEEK)
Polyethersulfone (PES)
Polyphenylenesulfide (PPS)
Polyaryletherketone (PAEK)

Extrusion Run Numbers:

Acutech (outside vendor)
#10-576-1
#10-556
N/A

Other Resins Included In The Analysis:

EVAL
Pebax 7233
Nylon 12
Isoplast
*Hytrel
PET

12-142
11-223
11-221
10-531-1
N/A
11-219-1

*Note: Hytrel was extruded but testing was stopped due to vendor agreement problems.

Tests:

- Tinius Olson Slope: This is the slope using angles 0,3,6,9.
- Tinius Olson Kink: Record the peak load value before it kinks and loses it's strength.
- Circle Kink: Put the tubing in a circle and continue to decrease the circle size while matching it to a circle template. Record the smallest circle the material would fit before kinking. This test should be used for reference only.
- Rupture pressure: Record the average rupture pressure.
- Mechanical: Modulus, elongation, and strength. Testing completed at ACS at room temperature.

Acceptance Criteria:

Tinius Olson Slope: Catheter having the highest number is considered the best.

Tinius Kink: Catheter having the highest number is considered the best.

Circle Kink: Reference information only.

Rupture Pressure: Catheter must be able to withstand a minimum of 350 psi. (Protocol located in E. Williams lab notebook)

Modulus & Strength: Having a high modulus & strength is considered having better stiffness for the shaft performance.

Elongation: This material property is best correlated with post processing operations. For now, tubing should have a minimum elongation of at least 50%. This number is based on the post processing conditions from prior experiments using in-house and Accutech PEEK extrusions.

Results:

See attached spreadsheets.

MS 6/9/94

Joseph C. Saturno

Conclusion:

Material Summary - Compared to PEEK:

EEK:

This material has the highest modulus (408-428kpsi), strength (15.3-16.2 kpsi), Tinius Olson slope (4.28) & kink angle (79 degrees). It also has a rupture pressure over 500psi with an elongation of 56-69%. In my opinion this is the best material of all the materials tested.

ES

Compared to PEEK this material does not have as high a modulus (408-428 kpsi vs 323kpsi). Tinius Olson slope is 2.21 compared to PEEK at 4.27 and the T/O kink angle is 45 degrees compared to PEEK's 79 degrees. This material has adequate rupture pressure at 500psi, plenty of elongation at 150%. It has a strength value of 15,200 psi compared to PEEK 15,300 - 16,200 psi.

PS:

Compared to PEEK this material does not have as high a modulus (408-428kpsi vs 297 kpsi). Tinius Olson slope is 2.63 compared to PEEK at 4.27 and the T/O kink angle is 44 degrees compared to PEEK's 79 degrees. Rupture pressure is OK at 411 psi. Elongation at 335% is acceptable. It has a strength value of 10,700 psi compared to PEEK 15,300-16,200 psi.

ebax:

This material has a poor Tinius Olson slope of .71 and a T/O kink angle of 17 degrees. The modulus was approximately 1/4 that of PEEK at 104 kpsi. Rupture pressure was adequate at 411 psi along with an elongation of 285%. It's strength compared to PEEK is 10,900 psi vs 15,300-16,200

soplast:

Compared to PEEK this material does not have as high a modulus (408-428 kpsi vs 314 kpsi). Tinius Olson slope is 3.01 compared to PEEK at 4.27 and the T/O kink angle is 59 degrees compared to PEEK's 79 degrees. Rupture pressure is OK at 387 psi. Elongation at 130% is acceptable. It has a strength value of 13,900 psi compared to PEEK 15,300 - 16,200 psi.

Joseph C. Chabano JCS 6/9/94

S. W. Wink 6/9/94

J. W. Wark 6/9/94

PET: Compared to PEEK this material does not have as high a modulus (408-428 kpsi vs 311 kpsi). Tinus Olson slope is 1.76 compared to PEEK at 4.27 and the T/O kink angle is 31 degrees compared to PEEK's 79 degrees. Rupture pressure is at 500+ psi. Elongation at 698% is acceptable. It has a strength value of 13,600 psi compared to PEEK 15,300 - 16,200 psi.

Nylon 12:

This material had a average rupture of 291 psi which is unacceptable. See spreadsheets for additional information

EVAL:

This materials has an unacceptable rupture pressure. When material came in contact with water at 37c it became very supple(noodle-like). Because of these results this material is found to be unacceptable. See spreadsheets for additional information

PAEK:

There were 3-4 attempts to extrude tubing and because of difficulties no tubing was obtained.

Recommendation:

Continue PEEK development efforts for the Next Generation .014" O-T-W. Continue in-house development efforts along with procuring material from Accutech. All materials tested do not have the performance that is comparable to PEEK. With regard to PEEK improvements, the only improvement that I can foresee would be to increase the elongation properties to improve post processing conditions. Optimizing the PEEK extrusion will start in June 1994 with Steve Schaible completing a DOE for extrusion conditions.

PAEK should be investigated at a later time.

Miscellaneous:

Material information for rupture data can be located in Eric William's lab notebook.

For information regarding the mechanical properties see Ted Slater in the Materials Department.

Additional information can be found in Larry Wasicek's lab notebook

Joseph Chazara 6/9/94

6/6/99 JCS

Material Properties

Information From Manufacture Property Data Sheet													
Test Method	Name/Grade	ASTM D638 Ten. @ Yield	ASTM D638 Ten. @ Break	Tensile Mod	ASTM D638 Elong. @ Yld	Ultimate Elong.	ASTM D790 Flex. Mod.	ASTM D570 Moist. Absb.	Rockwell Hardness	Comments			
Units		PS	KPS	KPS	Percent	Percent	KPS	Percent	Scale				
Advanced Resin:													
Polyetheretherketone (PEEK)	Victrax 381	N/A	13.5	N/A	4.9	50	594	0.50	N/A				
Polyulfone (PSF)	Udel-P3500	N/A	10.2	360	N/A	50-100	390	0.30	N/A				
Polyulfone (PSF)	Ultrason-S3010	11500	N/A	N/A	5.7	60-85	370	0.80	M-69	Mod. Elast. 390 kpsi			
Polyethersulfone (PES)	Ultrason-E3000	13000	N/A	N/A	6.7	15-40	370	2.10	M-85	Mod. Elast. 410 kpsi			
Polyethersulfone (PES)	Radel-R5000	N/A	10.1	340	7.2	60-120	350	0.37	N/A				
Polyetherimide (PEI)	Radel-A200	N/A	12	385	6.5	N/A	420	1.85	N/A				
Polyphenylenesulfide (PPS)	Ultem 1000	N/A	14.5	420	N/A	70	450	0.16	R-123	From J. Lee			
Polyaryletherketone (PAEK)	Ultrapak A-3000	N/A	12.5	N/A	4.5	N/A	600	0.01	M-93				
Polyphenylenesulfide (PPS)	Raylon	17110	N/A	N/A	5.2	N/A	N/A	0.80	D-86	Y. Mod. 580 kpsi			
Polyphthalamide (PPA)	AMODEL	glass filled only											
Resin:													
EVAL	L101	13655	10.4	455	N/A	200	N/A	N/A	N/A	From J. Lee			
EVAL	H101A	9365	6.7	341	N/A	280	N/A	N/A	N/A	From J. Lee			
EVAL	E105A	8535	7.4	299	N/A	280	N/A	N/A	N/A	From J. Lee			
Pebax	1147	N/A	9.1	N/A	N/A	N/A	133	N/A	N/A				
Phillips	Resin KR03	3700	N/A	N/A	N/A	160	205	0.09	Shore 65D				

Joseph C. Saturno JCS 6/9/94

Mat't data/shaft

Material	Extrusion #	Type	Room Temperature Data				
			Tensile			Compression	E ¹
			Strength (psi)	Elongation (%)	Modulus (psi)	Modulus (psi)	
PEEK	Acutech	QM	15,300	56%	408,000	149,000	3.63E-03
PEEK	Acutech	QM	16,200	69%	428,000	N/A	#N/A
PES	10-576-1	QM	15,200	150%	323,000	175,000	#N/A
FPS	10-556-1	QM	10,700	335%	297	147,000	#N/A
EVAL	12-142-A	QM	N/A	N/A	N/A	N/A	#N/A
EVAL	12-142-A Irrad.	QM	N/A	N/A	N/A	N/A	#N/A
NYLON 12	11-221-1?	QM	9,360	206%	144,000	79,000	1.65E-03
PET	11-219-1	QM	13,600	698%	311,000	138,000	3.14E-03
IsoPlast	10-531-1	QM	13,900	130%	314,000	131,000	3.05E-03
Pebax	10-560-1	QM	10,900	285%	104,00	52,400	#N/A
PAEK	Unable to extrude						

J. W. Wainwright 6/9/94

108 6/9/94

Test Results

Test Results - Data Sheet						
Test Method		Tinius Olson	Tinius Olson	Kink Angle Radius	Rupture Pressure	Kink & Pull
		Slope	Kink Angle			
Units			Degrees	Inches	PSI	Comments
Advanced Resin:						
Polyetheretherketone (PEEK)		4.27	79	9/16"	500+	GD
Polyethersulfone (PES)		2.21	45	1/2"	500+	GD
Polyphenylenesulfide (PPS)		2.63	44	7/8"	411	GD
Polyaryletherketone (PAEK)		N/A	N/A	N/A	N/A	N/A
EVAL		N/A	N/A	5/8"	123	OK
Pebax		0.71	17	7/16"	411	GD
Isoplast		3.01	59	15/32"	387	Separates easily
Nylon 12		1.04	24	1/2"	291	GD
PET		1.76	30	3/4"	500+	GD
Sample Size		3	3	2	5	2

JLH 6/9/94 Jugh & Edwards 6/11/94

J. Edwards 4/9/94

SCS 6/9/94 ~~Charles Sutermeister 6/9/94~~

Description FPS
Lot # _____
Operator and date LARRY WASICEK 5/19/94

Enter in moment weight 0.045
Enter in inherent weight 0.005
Enter in span 0.5

Note:
Inherent weight is .1 for 6" machine
Inherent weight is .005 for 1" machine

Raw Bending Data

		samples					Avg.	Std.Dev.
		#1	#2	#3	#4	#5		
Degrees	0	1	1	1			0	1.0
	3	7	9	9			3	8.3
	6	15	17	17			6	16.3
	9	23	26	25			9	24.7
	12	30	32	32			12	31.3
	15	36	39	39			15	38.0
Kink angle		43	44	46			<u>44</u>	
Slope (3,6,9) ref.		2.6667	2.8333	2.6667	#VALUE!	#VALUE!	2.7222	6/9/94
Slope (0,3,6,9)		2.4667	2.7667	2.6667	#VALUE!	#VALUE!	2.6333	
Inner diameter		.0325	.0325	.0325			.0325	
Outer diameter		.0385	.0385	.0385			.0385	

E (4PT) 221900 248900 239900 #VALUE! #VALUE! 236900

J. Wasicek 6/9/94

J. W. Wanda 6/9/94

Description	FES				
Lot #					
Operator and date	LARRY WASICEK 5/19/94				

Enter in moment weight	0.045	Note: Inherent weight is .1 for 6" machine Inherent weight is .005 for 1" machine
Enter in inherent weight	0.005	
Enter in span	0.5	

Raw Bending Data

samples

	#1	#2	#3	#4	#5		Avg.	Std.Dev.
Degrees	0	1	1			0	1.0	0.0
	3	7	7			3	7.0	0.0
	6	12	14			6	13.3	1.2
	9	21	21			9	21.0	0.0
	12	27	27			12	27.0	0.0
	15	32	32			15	32.0	0.0
Kink angle	44	45	45					
Slope (3,6,9) ref.	2.3333	2.3333	2.3333	#VALUE!	#VALUE!		2.3333	
Slope (0,3,6,9)	2.1667	2.2333	2.2333	#VALUE!	#VALUE!		2.2111	
Inner diameter	.0310	.0310	.0310				.0310	
Outer diameter	.0375	.0375	.0375				.0375	
E (4PT)	199900	206100	206100	#VALUE!	#VALUE!		204000	

6/9/94 Joseph C. Stalinski

Description PEEK
 Lot # ACUTEK
 Operator and date LARRY WASICEK 5/19/94

Enter in moment weight 0.045
 Enter in inherent weight 0.005
 Enter in span 0.5

Note:
 Inherent weight is .1 for 6" machine
 Inherent weight is .005 for 1" machine

Raw Bending Data

samples

degrees

	#1	#2	#3	#4	#5		Avg.	Std.Dev.
0	1	1	1			0	1.0	0.0
3	14	14	14			3	14.0	0.0
6	27	27	24			6	26.0	1.7
9	40	40	39			9	39.7	0.6
12	50	50	50			12	50.0	0.0
15	60	60	60			15	60.0	0.0

Kink angle

81 80 76

Slope (3,6,9) ref.

4.3333 4.3333 4.1667 #VALUE! #VALUE!

4.2778

Slope (0,3,6,9)

4.3333 4.3333 4.1333 #VALUE! #VALUE!

4.2667

Inner diameter

.0325 .0325 .0325

.0325

Outer diameter

.0400 .0400 .0400

.0400

E (4PT)

291800 291800 278400 #VALUE! #VALUE!

287300

JS 6/9/94 Joseph C. Saturnio 6/9/94

L. Wasicek 5/19/94

Memorandum

Date: January 14, 1994
To: Distribution
From: Larry Wasicek *LW*
Subject: Minutes from the next generation .014" OTW brain storming meeting -1/13/94.

The purpose of this meeting was to begin generating ideas that could possibly replace the Elastinite hypotube which is currently being reviewed.

The following ideas/discussions were derived from the brain storming session:

- There is no other hypotube materials that perform like Elastinite.
- Continue investigating PEEK as a IM & OM (coaxial design). Bob Ainsworth to contact vendor about round dual lumen PEEK extrusions.
- In house extrusions: round dual lumen made with PETG, PET, Hytel, and Nylon.
- Larry to investigate patents that use Nylon for shafts and IMs.
- Elastinite reinforcing mandrel to be prototyped in a quad lumen extrusion (Larry). Extrusion request submitted 12/21/93.
- Elliptical reinforced inflation/deflation. Process: braided single lumen inflation/deflation, single lumen guide wire lumen, with a heat shrink jacket.
- Next week, Hudson Industries is sending B. Ainsworth samples of polyimide with wound and braided stainless having an ID/OD of .019/.024"
- J. Lee discussed the possibilities of extruding reinforcing mandrel in the IM/OM walls- it is possible.
- Over braid on an elliptical or round dual lumen shaft.
- There was some discussion about the extrusion, braid, and extrusion process. The concerns are the wall thickness and cost. It doesn't seem to be a feasible option.
- Graphite IM not a suitable candidate.

Any questions, concerns, or ideas please let me know.

Thank you.

Distribution:

J. Chiu	*J. Lee
*D. Cox	*B. Ainsworth
*E. Peterson	*J. Becker
*R. Cherry	*E. Leopold
*S. Levin	Z. Chen

*Denotes attendee

J. Wasicek 6/9/94

Joseph C. Sartorius 6/9/94
6/9/94

*Selective resins
seen optimizing*

Memorandum

Date: March 2, 1994

To: Distribution

From: Larry Wasicek *LW*

Subject: Minutes from the advanced thermoplastics meeting 3/1/94.

The purpose of this meeting was to discuss and select advanced thermoplastics that may be candidates/options to Elastinite hypotube technology that is being considered for the next generation OTW/RX platform catheters.

- Elastinite is still a viable design option, but there are deep concerns regarding material & processing costs.
- The ACX V catheter shaft requirement/specifications dated 3/8/93 was distributed. Team members are to red line the ACX V shaft specification with any changes and give them to Dan by Friday (3/4/94). Dan to provide new specification.
- Reviewed material property data matrix.
- **Selected resins to investigate:**
 - PEEK tubing to arrive this week. (outside vendor) *- Rec'd 3/1/94 Transition development*
 - PEEK resin is available for in house extrusion. *Extrude 3/7-11 per D. Hock.*
 - Polyethersulfone (PES) Radel - R5000. *Larry to order 10lb 3/11/94*
 - Polyaryletherketone (PAEK) Ultrapak A-3000. *Larry to order 10lb 3/11/94*
 - Polyphenylenesulfide (PPS). *Fortron* *Larry to order 10lb 3/11/94 - due date*
 - Polyetherimide (PEI) Ultem 1000. *order different resin* *Larry to identify outside vendor.*
 - *(+) glass filled resin.* Larry, Bob and Jeong to identify resin this week and order *(IMS)*
- Larry to investigate the tape wrapping process and vendors.
- Resins properties can be modified with graphite easier than adding plasticizers.
- Areas of concern: biocompatibility, sterilization

Next meeting 3/16/94. topics include:

- Time line - Larry
- Present shaft design specification - Dan
- Tape wrapping process - Larry
- Outside extrusion services - Bob/Jeong

If you have any questions, concerns, or ideas that you would like discussed at the next meeting please let me know so I can add them to the agenda.

Thank you.

Distribution:

- | | | |
|----------------|------------------|------------|
| • J. Lee* | M. Buchin | *D. Cox |
| • B. Ainsworth | R. Cherry | *Z. Chen |
| • J. Becker | *G. Schneiderman | B. Saltman |

*E. Leopold
*Denotes they attended

*- Call Art
- Flo Tech
- Adam Spence*

*- Putnam
- AES*

*Screen resist then optimizing
Q O.T.W. dual - RX shaft.*

*min
7 day
wks*

*Caton
+ TFE*

*- Putnam
dual*

Joseph C. Sattone 3/1/94

J. Wasicek 3/1/94

3/16/94

due in 1/4 month